

REMARKS

Please enter this Amendment and Response and reconsider the rejection of the claims.

Applicant has amended claims 25 and 44 to clarify the subject matter of the claims. Applicants submit that the amendment is supported throughout the specification.

Applicant has cancelled claims 29, and 45-48 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Applicant has added new claims 49-52. Applicant submits the newly presented claims are supported throughout the specification, including at page 11, lines 25-35; page 14, lines 7-25; page 26, line 8 to page 27, line 25; and page 35, lines 9-23.

Applicant has amended the specification to update the priority claim.

35 U.S.C. § 102(b)

The Examiner rejected claims 25, 38, 44 and 46-48 under 35 U.S.C. § 102(b) as being anticipated by Bodmer (WO 98/01974).

Applicant's claim 25 is now directed to a F(ab')₂, wherein each Fab' comprises a CH1 domain fused to an amino acid sequence of up to 10 amino acids, wherein the amino acid sequence of up to 10 amino acids comprises a C terminal amino acid sequence of Cys-Ala-Ala. None of the sequences of Bodmer comprise a C terminal sequence of Cys-Ala-Ala. Applicants submit Bodmer et al. does not teach or suggest such a F(ab')₂.

Applicants submit that claim 44 and newly presented claim 49 are not anticipated by Bodmer et al, in the least, because these claims refer to expressing a nucleic acid in a microbial host cell. The Fab' or F(ab')₂ product is different than that of Bodmer et al., in the least, because these products lack glycosylation. In addition, the claims also specify the Fab' produced comprises a CH1 domain fused at its C terminus to an amino acid sequence of up to 10 amino acids, wherein the amino acid sequence comprises a C terminal amino acid sequence Cys-Ala-Ala. Applicant submits Bodmer et al. does not disclose a Fab' with these characteristics.

For at least these reasons, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(b) rejection.

35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 25, 29, 39 and 44-48 for being indefinite. Applicant traverses.

The Examiner contends that it is unclear what is meant by an amino acid sequence of 1 to 10 amino acids and comprising a C terminal amino acid sequence of Cys-X-X. While not acquiescing in the rejection and solely to expedite prosecution, Applicant has amended the claims to refer to up to 10 amino acids, rendering the rejection moot. Applicant respectfully requests withdrawal of the rejection.

The Examiner also rejected claims 44-48 as indefinite, because the Examiner contends the claims do not clearly set forth the composition. While not acquiescing to the rejection and solely to expedite prosecution, Applicant's claim 44 now refers to a composition comprising a monospecific F(ab')₂, rendering the rejection moot. Applicant respectfully requests withdrawal of the rejection on this basis.

35 U.S.C. § 112, First Paragraph

The Examiner rejected claim 47 under 35 U.S.C. § 112, first paragraph. The Examiner contends that a heterologous molecule, such as a toxic drug or toxin, is not supported in the specification and is new matter. Applicant respectfully traverses.

Applicant submits that at page 27 of the specification, the specification discloses that a Fab containing polypeptide can comprise an immunotoxin. The specification also indicates that a bifunctional agent, such as SPDP, can be used to couple the immunotoxin and Fab indicating such coupling could proceed through thiol groups. Thus, Applicant has support for coupling of toxins and cytotoxic drugs to Fab using a free sulfhydryl group. Applicant respectfully requests withdrawal of the rejection on this basis.

Interview

Applicant requests an interview with the Examiner and his supervisor. Upon receipt of these papers, Applicant requests that the Examiner call Applicant's representative to schedule the interview.

Summary

Applicant submits the claims are in condition for allowance and notification to that effect is earnestly solicited. Applicant requests that the Examiner contact Applicant's representative if prosecution may be assisted thereby.

Respectfully submitted,

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